IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number	:	10/535,500	Confirmation No.:	7327
Applicant	:	Anne Mette Buhl HERTZ, et al.		
Filed	:	May 26, 2005		
Title	:	METHODS AND KITS FOR DIAGNOSING AND TREATING B-CELL CHRONIC LYMPHOCYTIC LEUKEMIA		
TC/Art Unit	:	1643		
Examiner:	:	Anne Gussow		
Docket No.	:	55320.001041		
Customer No.	:	**21967**		

Commissioner for Patents
P.O. Box 1450
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FURTHER RESPONSE TO RESTRICTION AND NON-RESPONSIVE NOTICE REQUIRING ELECTION OF A NUCLEIC ACID SEQUENCE SPECIES FOR PURPOSES OF EXAMINATION

Sir:

This Reply is further Responsive to the Restriction Requirement mailed on April 23, 2007, and Applicants' Election Response on July 23, 2007 wherein Applicants elected Group I with traverse. The traversal was on the basis that the Restriction Requirement violates the PCT rules and US restriction practice governing patent applications filed under 35 USC 371 since it is in conflict with Article 127(1) of the PCT wherein it is stated that no national law shall require compliance with requirements correlating to the form or context of the international application different from or additional to those in which are provided in the Treaty and the Regulations. Article 27(1) is further clarified in the PCT guidelines under Item 138, wherein it is stated that an international application which complies with the unity of invention requirement laid down in Rule 13 PCT must be accepted in all the designated and elected offices. Applicants' previous traversal and remarks are incorporated by reference herein.

After submission of this Response the undersigned was contacted telephonically by the Examiner who indicated that the Election response was non-responsive by failing to elect a

particular nucleic acid sequence for purposes of examination. Also, a Notice was mailed on August 20, 2007 requesting an Election of Species. This Response includes the requested species election.

For purposes of satisfying the requirement Applicants elect for purposes of examination the nucleic acid sequence contained in SEQ ID NO:11 which corresponds to a detected transcriptional product which is encompassed by the elected assay methods. This sequence is recited in Claim 50 which depends from claim 49 which in turn depend from claims 43, 44, 45, 46 or 47. However, Applicants respectfully request that on a determination of allowability that the Examiner extend the search to the other sequences recited in the claims.

With respect thereto, Applicants note that the sequences in SEQ IDs no. 12 to 18 correspond to single AMB1/CLLU1 exon sequences, which never exist as "single transcripts", rather all AMB1/CLLU1 transcripts, except 1, are composed of several exons. All exons are present within the genomic sequence included in SEQ ID no. 5. It has been discovered that there is a primary AMB1/CLLU1 transcript that at least covers from pos. 8,950 to pos. 71,099 in the sequence included in SEQ ID No. 5. Therefore, any transcript that includes the sequence from the start of the AMB1/CLLU1 primary transcript (pos. 8,950 in SEQ ID no. 5) as the first exon, can be used for B-CLL diagnostics. At least in view thereof Applicants believe that the recited group of sequences in the elected claims correspond to a single unitary invention.

With particular respect to the elected sequence, this cDNA sequence corresponds to a transcript the inventors have detected to be present in CLL cells, and which includes must of the sequences relevant for B-CLL diagnostics, i.e., SEQ ID No. 11. By use of SEQ ID No:11 only one single exon is potentially not detected from an "odd" down-stream cDNA. Expression of that cDNA also give "the prognosis", but ONLY if exon 1 is used as the first exon. Exon 1 is part of both SEQ IDs 1, 5 or 11.

As noted, there is a single exon which potentially is not detected using assays limited to detecting SEQ ID No. 11. This exon also forms part of another mRNA, which starts another place. For the foregoing reasons, Applicants respectfully submit that the Examiner at least extend her search to assays which detect for any one of the transcription products contained in SEQ ID NO: 1, 5 or 11 as this provides for a more comprehensive and biologically relevant assay.

It is believed that this species election should make Applicants' Restriction Response complete. Also, for the reasons articulated in Applicants' previous Election Reply Applicants

respectfully request that Groups I, II and VI be rejoined and examined together in response to the Election response submitted herewith. Further, in order to expedite prosecution on the merits Applicants have previously cancelled claims 1-42 without prejudice and have submitted new claims 43-60 all of which are believed to correspond to the elected subject matter which defines a unitary invention according to the PCT guidelines.